DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FEB 18 2000

0399 '00 FEB 22 P3:17

Kenneth C. Cancellara, Q.C.
Senior Vice President & General Counsel
Biovail Corporation International
2488 Dunwin Drive
Mississauga, Ontario L5L 1J9
Canada

Re: Docket No. 99P-2778/CP1

Dear Mr. Cancellara:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received by the Dockets Management Branch on August 4, 1999. You request that the Agency adopt a policy of publicizing on the Internet certain standardized information whenever an abbreviated new drug application (ANDA) is submitted to the Agency containing a paragraph IV certification that would qualify for generic 180-day exclusivity.

The Agency is still evaluating the request made in your petition, and we will respond once this process is completed. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-2778

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